

**PRELIMINARY AMENDMENT
ATTORNEY DOCKET NO. 1/1148-2-C2**

CLAIM AMENDMENTS

IN THE CLAIMS:

1. (Original) Crystalline tiotropium bromide monohydrate.
2. (Currently Amended) Monoclinic crystalline~~Crystalline~~ tiotropium bromide monohydrate according to claim 1, ~~having an endothermic peak at $230^{\circ}\text{C} \pm 5^{\circ}\text{C}$ occurring during thermal analysis using DSC at a heating rate of 10K/min .~~
3. (Currently Amended) Monoclinic crystalline~~Crystalline~~ tiotropium bromide monohydrate according to claim 1, having a primitive lattice type~~an IR spectrum comprising bands at wave numbers $3570, 3410, 3105, 1730, 1260, 1035$, and 720cm^{-1} .~~
4. (Currently Amended) Monoclinic crystalline~~Crystalline~~ tiotropium bromide monohydrate according to claim 2, having 4 formula units per elementary cell~~an IR spectrum comprising bands at wave numbers $3570, 3410, 3105, 1730, 1260, 1035$, and 720cm^{-1} .~~
5. (Cancelled)
6. (Cancelled)
7. (Cancelled)
8. (Cancelled)
9. (Currently Amended) A process for preparing monoclinic crystalline tiotropium bromide monohydrate, the process comprising:
 - (a) dissolving tiotropium bromide in water to obtain a solution;
 - (b) heating the resulting solution;
 - (c) adding activated charcoal to the heated solution;
 - (d) removing the activated charcoal; and

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(e) allowing the solution to slowly cool to obtain monoclinic crystalline tiotropium bromide monohydrate.

10. (Currently Amended) A process for preparing monoclinic crystalline tiotropium bromide monohydrate, the process comprising:

(a) dissolving tiotropium bromide in water to obtain a solution;

(b) heating the resulting solution to more than 50°C;

(c) adding activated charcoal to the heated solution;

(d) removing the activated charcoal; and

(e) allowing the solution to slowly cool to obtain monoclinic crystalline tiotropium bromide monohydrate.

11. (Original) The process according to claim 10, wherein 0.4 to 1.5 kg of water are used per mole of tiotropium bromide in step (a).

12. (Original) The process according to claim 11, wherein 10 g to 50 g of activated charcoal per mole of tiotropium bromide is added in step (c).

13. (Original) The process according to claim 12, wherein the activated charcoal added in step (c) is stirred for between 5 and 60 minutes before it is removed in step (d).

14. (Original) The process according to claim 13, wherein step (d) is performed by filtration of the solution.

15. (Original) The process according to claim 14, wherein the solution of step (e) is cooled to a temperature of 20°C-25°C at a cooling rate of 1 to 10°C per 10 to 30 minutes.

16. (Currently Amended) A pharmaceutical composition comprising an effective therapeutic amount of crystalline tiotropium bromide monohydrate ~~according to claim 1~~ and a pharmaceutically acceptable excipient.

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17. (Currently Amended) A method for treatment of diseases selected from the group consisting of allergic, anti-inflammatory, respiratory, genitourinary, CNS, ophthalmic, gastrointestinal, and nausea and vomiting ~~in which the administration of an anticholinergic agent may have a therapeutic benefit, in a patient in need of such treatment,~~ which method comprises administering to a the patient an effective therapeutic amount of a compound according to claim 1.

18. (Original) The method according to claim 17, wherein the disease is asthma or COPD.

19. (Currently Amended) A process for preparing monoclinic crystalline hydrates of tiotropium bromide, the process comprising:

- (a) dissolving tiotropium bromide in water to obtain a solution;
- (b) heating the resulting solution; and
- (c) allowing the solution to slowly cool to obtain monoclinic crystalline hydrates of tiotropium bromide.

20. (Currently Amended) A process for preparing monoclinic crystalline hydrates of tiotropium bromide, the process comprising:

- (a) dissolving tiotropium bromide in water to obtain a solution;
- (b) heating the solution of step (a);
- (c) adding activated charcoal to the heated solution of step (b);
- (d) removing the activated charcoal from the solution of step (c); and
- (e) allowing the solution to slowly cool to obtain monoclinic crystalline hydrates of tiotropium bromide.

21. (Original) The process of claim 20, wherein the solution of step (a) is heated to more than 50°C.